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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,150	12/10/2003	Chia Soo	62855.4	8266
7590		10/31/2007		
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			ART UNIT	PAPER NUMBER
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			10/31/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/733,150

Applicant(s)

SOO, CHIA

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 28-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-05-07 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-51 are presently pending. Claims 1-16 and 28-51 are withdrawn from further consideration for the reasons of record. Claims 17-27 are currently under examination.

### ***Summary of Interview***

4. Applicant's description of the telephonic interview of July 31, 2007, did not clearly set forth that the examiner emphasized that despite differences of intended use, that absent evidence to the contrary, if the prior art disclosed the claimed composition, it would read on the claimed invention.

**Response to Amendment**

**Claim Rejections - 35 USC § 112**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 17-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter).

In the amendment filed 9-05-07 Applicants amended the instant claims to recite wherein the claimed composition comprises a proteoglycan compound in the range of "up to about 10%" by weight of the total composition. However, it is noted that Applicants do not point out where in the specification or in the original claims, support can be found for this amendment.

Although there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, Wertheim, 541 F.2d at 262, 191 USPQ at 96; however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims. See MPEP § 714.02 and § 2163.06 ("Applicant should \* \* \* specifically point out the support for any amendments made to the disclosure."); and MPEP § 2163.04.

Moreover, after a text search of the specification as filed for the newly added claim limitations, support for this amendment could not be found. It is therefore concluded that Applicant's amendment is considered new matter. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 103***

7. Claims 17-27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ruoslahti et al. for the reasons of record.

8. Applicant's arguments filed 9-05-07 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that Ruoslahti et al. does not describe or teach a composition comprising a proteoglycan up to about 10% by weight of the total composition that is effective for skin generation in a skin damaged by skin inflammation, skin pigmentation, dermal collagen disorganization, and aging.

9. In response to applicant's argument that the claimed composition comprising up to about 10% by weight of a proteoglycan defines a non-obvious composition that is particularly effective for damages to skin by skin inflammation, skin pigmentation, dermal collagen disorganization, and aging, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior

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art. If the prior art structure is capable of performing the intended use, then it meets the claim.

10. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

11. To the extent that the instant claims are drawn to a product, the intended use of Applicant's claimed invention does not appear to impart some structural difference between the claimed composition, and the prior art composition. Apart from the intended use limitations, the claimed composition is essentially drawn to: a composition comprising a proteoglycan compound up to about 10% by weight of FM, lumican, decorin, biglycan, and combinations thereof, and further comprising from about 0.1% to about 80% by weight of a cell lysate, extract, or media enriched with the proteoglycan compound, from about 0.1% to about 10% by weight of hyaluronic acid; up to about 10% by weight of at least one skin care agent, and a carrier.

Ruoslahti et al. discloses compositions for the **prevention** or reduction of scarring by administration of compositions comprising decorin or a functional equivalent of decorin, to a wound (see page 5, lines 17-26). Functional equivalents of decorin include the following (see page 14, lines 21-28):

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Functional equivalents of decorin include modifications of decorin that retain its functional characteristics and molecules that are homologous to decorin, such as biglycan and fibromodulin, for example, 25 that have the similar functional activity of decorin. Modifications can include, for example, the addition of one or more side chains that do not interfere with the functional activity of the decorin core protein.

Fibromodulin is clearly disclosed as useful in the compositions of Ruoslahti et al., wherein said compositions are used for skin care. Moreover, to the extent that the compositions of Ruoslahti et al. are useful to *"prevent"* scarring, the compositions are interpreted as useful in the absence of a dermal wound.

As stated in the prior Office Action, it would have been obvious to the ordinary skilled artisan at the time of the instant invention to modify the teachings of Ruoslahti et al. to comprise the various weight percentages of the individual components in the design of the instant invention. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2144.05 [R-5], which states: "[G]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical." In the instant case, there is no evidence of unexpected results in regards to skin regeneration in the absence of a dermal wound, associated with compositions comprising a range from about 0.0001% to about 10% proteoglycan that will support

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applicant's claim of patentability over the compositions of Ruoslahti et al. Applicant's arguments do not take the place of evidence of unexpected results that would be indicative of the non-obviousness of the claimed compositions over the prior art.

12. Claims 17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soo et al.

13. Soo et al. teach that potential strategies for the manipulation of adult wounds into being more "fetal-like" (i.e. wherein healing comprises avoiding scar formation), may include the addition of *fibromodulin* to modulate both TGF- $\beta$  activity and extracellular matrix assembly.

The teachings of Soo et al. clearly teach the use of fibromodulin for wound repair without the formation of scar tissue. Soo et al. differs from the instant invention to the extent that it does not teach compositions comprising up to 10% by weight of a proteoglycan compound.

It would have been obvious to the ordinary skilled artisan at the time of the instant invention to modify the teachings of Soo et al. to design a composition comprising up to 10% by weight of a proteoglycan compound. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2144.05 [R-5], which states: "[G]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical."



***Claim Rejections - 35 USC § 112***

14. The rejection of claims 23-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment. However, due to Applicant's amendment filed 9-05-07, a new grounds of rejection is set forth below.

15. Claims 23-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-27 are indefinite to the extent that it is unclear if Applicants intended to limit the scope of claim 17, or if they intended to claim a distinct composition from claim 17 since the scope of claims 23-27 are broader than the scope of claim 17. For example, claim 17 limits the proteoglycan compound of the composition to up to about 10% by weight of the total composition, however claim 23 recites wherein the skin care composition of claim 17 *further comprises* 0.1% to about 80% by weight of a cell lysate, extract or media enriched with the proteoglycan compound.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner  
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JLE